Mini Lap Technologies Inc.

K132232

510(k) Summary
(as specified by 21 CFR 807.92)
Prepared July 11, 2013,
Modified December 3, 2013

DEC 0 4 2013

Device Name: MiNS Needlescopic Resposable Laparoscopic device system

Intended Use

The MiNS grasping instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold, and manipulate other soft internal tissues as well as items such as hernia mesh.

No Previous NSE Decision

This device has not been the subject of a previous NSE decision nor has there been other submissions or communication to the FDA regarding this device..

Establishment Registration Number

Regulatory Contact
Allan Alward
145 Palisade Street
Dobbs Ferry, NY 10522

Sponsor/Manufacturer
Mini Lap Technologies Inc.
145 Palisade Street
Dobbs Ferry, NY 10522
Contact: Dr. S. Ravikumar
Tel: 914.591.8400

FDA Establishment Registration Number is 3007123990

Device Trade or Proprietary Names

The device trade names are: MiNS Needlescopic Resposable Laparoscopic device system

Device Common, Usual or Classification Names

Laparoscopic Instruments, Graspers, Cannula, Trocar, Manual Surgical Instruments.

Classification Panel

Classification of this device falls under the responsibility of the General & Plastic Surgery panel.

Class

Class 2 device under the following product codes/regulations:

- OCW, 21 CFR 876.1500, Endoscope and accessories

Applicable Standards

Compliance with Section 514 of the Food, Drug and Cosmetic Act

None. Section 514 has not established performance standards for this device.

Device Description

Summary of the function of the device and its major components:

The MiNS devices are a family of disposable and re-useable devices. Consisting of an integrated, insulated needle/cannula shaft that houses a retractable grasper (NLU) which are inserted into a reusable Handle. The disposable NLU's when inserted into a reusable Handles are used for mobilization and manipulation of soft tissue during general laparoscopic procedures. The system has the ability to directly penetrate soft tissue to access certain areas of the human anatomy without the need for a traditional insertion conduit. The shaft of the instrument can be introduced percutaneously to the surgical site, after which the working portion of the instrument can be deployed to approximate, grasp and manipulate soft tissue.

Patient Contact Materials

The device is composed of biocompatible materials that have been used in medical devices for many years. The patient contact materials are biocompatible and are identical to the predicate Minilap device (K070686) which passed testing to ISO 10993.

Cleaning, Disinfection, Sterilization and Pyrogenicity

The MiNS Needlescopic Resposable Laparoscopic device NLU's are a family of sterile disposable single patient packaged in a pet blister tray and sealed with a tyvek lid for the sterile barrier use ends that attaches to an autoclavable reusable handle.

The MiNS Needlescopic Resposable Laparoscopic device Handle is a reusable autoclavable portion of the MiNS system which has separate cleaning and sterilization techniques located in the information booklet and is packed as a non sterile device in a separate package..

The Handle portion is designed for moist heat sterilization, validated in production to an SAL of 10^{-6} per ISO 17665:2006 utilizing a half cycle overkill method to meet the requirements of ISO17665-1:2006, Steam sterilization of medical devices.

The disposable NLU's are sterilized using gamma radiation, validated in production to a SAL of 10^{-6} per ISO 11137:2006, Method 1, in order to reduce gamma exposure/aging. When applicable, the VDmax provisions of 11137:2006 will be used to substantiate the standard 25-to-40 kGy dose.

Software

The subject device does not include software.

510(k) Summary of Safety and Effectiveness

We have compared various characteristics of the MiNS Needlescopic Resposable device system to existing technologies that would have an adverse affect upon the safety and efficacy of the system and have found that the Mini Lap MiNS Needlescopic Resposable device system does not present any new risks to the patient and therefore, we believe that it is substantially equivalent to other devices and technologies cleared by the FDA.

Technological Characteristics

Mini Lap Technologies, Inc. believes that the subject device is substantially equivalent to other devices that have previously received FDA 510(k) clearance including the predicate devices.

Predicate Device

The following devices have been identified as predicate devices:

- Mini Lap Instruments – K070686
- Snowden-Pencer-Resposable Laparoscopic Scissors- K113407
- Aesculap Needlescopic Instrument System- K982623

Predicate Device Comparison

The Mini Lap MiNS Needlescopic Resposable device systems are, in principal and function, identical to existing technologies. A variety of reusable laparoscopic instruments are already widely manufactured and used in surgical procedures and have many similarities to the MiNS Needlescopic Resposable device system.

Discussion on Comparison:

Mini Lap Instruments

The Mini Lap Instruments (K070686) were included as predicates as part of the comparison because the needle design and jaw design dimensions as well as the patient contact materials are identical to the subject device along with sterilization method.

- The main differences between the Mini Lap Instruments and the MiNS Needlescopic Resposable device system are the a) handle design which is reusable , b) the grasper shaft assembly attaches to a reusable handle .

Snowden-Pencer Resposable Laparoscopic Scissors (K113407) were included as predicates because they are a family of products with a reusable handle and sterile disposable tips indicated for mechanically cutting soft tissue in laparoscopic procedures.

- The two sets of devices share similar handle design, composed of Medical Grade stainless steel and plastic components.
- The main difference between the MiNS Needlescopic Resposable device system and the Snowden-Pencer Resposable Laparoscopic device is the outer diameter of the subject device is 2.4mm and the predicate is a 5mm.

Aesculap Needlescopic Instrument System (K982623) were included as predicates because they are a family of products with a reusable handles and attachable Shafts/tips indicated for use in endoscopic and laparoscopic procedures.

- The main difference between the MiNS Needlescopic Resposable device system and the Aesculap Needlescopic Instrument System is the Aesculap system is reusable.

In the following section, we compare various characteristics of the MiNS Needlescopic Resposable device system to existing technologies. The Mini Lap MiNS Needlescopic Resposable device system does not present any new risks to the patient and therefore, we believe that it is substantially equivalent to other devices and technologies cleared by the FDA.

Predicate Comparison Chart

Characteristic	**Mini Lap Technologies** **MiniLap Resposable Devices**	**Aesculap Needlescopic instruments**	**Mini Lap Technologies** **MINI LAP Instruments**	**Snowden-Pencer** **Resposable Laparoscopie Scissors**
510(k)	K132232	K982623	K070686	K113407
Use	The MiNS grasping instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold, and manipulate other soft internal tissues as well as items such as hernia mesh.	The Aesculap Needlescopic instrument set is indicated for use in adult and pediatric diagnostics and therapeutic general endoscopy and laparoscopy surgery.	The Minilap instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold, and manipulate other soft internal tissues as well as items such as hernia mesh.	The Snowden Pencer Laparoscopic Ergonomic Resposable Scissors is a monopolar electrosurgical instrument indicated to be used in general laparoscopic and gynecologic procedures to allow high frequency monopolar cutting and coagulation. The Resposable scissors are indicated to mechanical cut tissue and suture.
Needle diameter	2.4mm ± .1mm	2.5 mm	2.4mm ± .1mm	5mm
Device length	300 mm	Various	300 mm	24CM,36CM,45CM
Material Composition	Medical Grade Stainless Steel 17-7 SS, 300 SS,	Medical Grade Stainless Steel	Medical Grade Stainless Steel Polyester	Medical Grade Stainless Steel MT500 Polyolefin

	475SS, Polyester			
Sterilization	Autoclavable, non sterile, reusable handles with attachable disposable sterile, single use shaft tip combinations.	Non sterile, reusable detachable ends	Sterile, single use	Autoclavable, non sterile reusable handle Single use sterile disposable shaft and scissors tip

Table of Contents

A table of content is included at the beginning of this submission. The pages referred to in the contents correspond to the sequentially numbered pages of this premarket notification.

Truthful and Accurate Statement

A "truthful and accurate" statement regarding all information provided in this premarket notification is present on page .

Confidentiality

Mini Lap Technologies Inc. considers certain information in this premarket notification to be confidential business information, and has taken measures to protect the release of this information. Mini Lap Technologies Inc. requests the FDA respect the confidentiality of this information to the extent possible under law. We expect the FDA will consult with Mini Lap Technologies Inc. prior to the release of any information in this premarket notification (outside the 510(k) summary) for any reason, including requests under the Freedom of Information Act.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed a variety of bench tests for mechanical and attribute evaluations. Additionally, the device is composed of biocompatible materials with a history of usage in the medical device industry and share common design components with K070686.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minimal and conclude that the subject device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 4, 2013

MiniLap Technologies, Inc.
Mr. Allan Alward
Vice President, Research and Development
145 Palisade Street
Dobbs Ferry, New York 10522

Re: K132232
Trade/Device Name: MiNS Needlescopic Resposable device system
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCW
Dated: October 29, 2013
Received: November 5, 2013

Dear Mr. Alward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Mini Lap Technologies Inc.

Indications for Use

510(k) Number: K132232

Device Name: MiNS Needlescopic Resposable device system

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The MiNS grasping instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold, and manipulate other soft internal tissues as well as items such as hernia mesh.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.11.22 07:56:16 -05'00'

for BSA

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132232